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Division of Medical Assistance Sterilization Procedures

Clinical Coverage Policy No.: 1H Original Effective Date: January 1, 1974 Revised Date:

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Division of Medical Assistance Sterilization Procedures Clinical Coverage Policy No.: 1H Original Effective Date: January 1, 1974 Revised Date:

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1.0 Description of the Procedure

Sterilization is any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

1.1 Tubal Procedure

Female sterilization, also called tubal occlusion or ligation, is a permanent contraceptive method for women who do not want more children. The method requires a simple surgical procedure that prevents the egg from passing down the fallopian tubes into the uterus. A doctor can block the fallopian tubes several different ways. They can be clipped closed with bands or rings. They can be cut and tied closed, or they can be cauterized with an electric needle. Once the fallopian tubes are cauterized, scar tissue forms, which blocks them. A surgical cut must be made in either the abdomen just above the pubic hair, in the belly button and lower abdomen, or in the back wall of the vagina. The procedure can be done using a local anesthetic to numb the area, or a general anesthetic. The two most common female sterilization approaches are minilaparotomy, which is usually performed under local anesthesia with light sedation, and laparoscopy, which requires general anesthesia.

1.2 Hysteroscopic Procedure

The hysteroscopic approach to permanent sterilization, also known as the Essure System, does not require an incision or general anesthesia. It is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. A hysteroscope is inserted through the vagina and cervix into the uterus for direct visualization. Next, a small catheter with the micro-insert mounted at the tip is inserted through the hysteroscope into each of the fallopian tubes (one at a time) and the micro-inserts are released. The micro-inserts irritate the lining of the fallopian tube, causing the growth of scar tissue and the eventual permanent blockage of the fallopian tube.

1.3 Vasectomy

Vasectomy is an operation designed to make a male sterile by making small incisions in the skin of the scrotum, under a local anesthetic. The vas deferens is severed and the scrotal incision closed. The entire procedure is repeated on the opposite side.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 Gender and Age

Sterilization procedures are covered for both men and women age 21 and over.

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2.3 Mental Competency

The recipient must be mentally competent.

Note: If a judicial court orders a sterilization for a recipient who is a ward of the county, and is mentally incompetent, Medicaid is not responsible for the reimbursement of the sterilization.

2.4 Undocumented Aliens

Undocumented aliens are eligible for Medicaid emergency services only. Sterilization procedures are not considered an emergency service. Therefore, undocumented aliens are not eligible for sterilization procedures.

2.5 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination**. A screening examination includes any evaluation by a physician or other licensed clinician. EPSDT does not require the state Medicaid agency to provide any service, product, or procedure that is unsafe, ineffective, or experimental/investigational.

Service limitations on scope, amount, duration, and/or frequency and other specific criteria described in clinical coverage policies may be exceeded or may not apply provided documentation shows that the requested service is medically necessary to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination.

**EPSDT and Prior Approval Requirements

- 1. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- 2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT Provider Page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.0 When the Procedure Is Covered

Important Note: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination (**subject to prior approval requirements**, **if applicable**). For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy or visit the DMA Web sites specified below.

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Basic Medicaid Billing Guide: http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT Provider Page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.1 General Criteria

Medicaid covers sterilization procedures when:

- 1. the recipient meets the eligibility requirements listed in **Section 2.0**;
- 2. the procedure is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- 3. the procedure can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
- 4. the procedure is furnished in a manner not primarily intended for the convenience of the recipient's caretaker, or the provider; and
- 5. the procedure is provided according the federal regulations listed in 42 CFR 441.250 through 259 (http://www.gpoaccess.gov/cfr/index.html).

3.2 Hysterosalpingogram

For recipients who have undergone the Essure sterilization procedure, Medicaid covers a separate hysterosalpingogram (HSG) to confirm occlusion of the fallopian tubes, three to four months after placement of the micro-inserts.

4.0 When the Procedure Is Not Covered

Important Note: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination (**subject to prior approval requirements**, **if applicable**). For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy or visit the DMA Web sites specified below.

Basic Medicaid Billing Guide: http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT Provider Page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

4.1 Sterilization Procedures

Sterilization is not covered when:

- 1. the recipient does not meet the eligibility requirements listed in **Section 2.0**.
- 2. the recipient does not meet the medical necessity criteria listed in **Section 3.0**.
- 3. the procedure is not provided according to the federal guidelines listed in 42 CFR 441.250 through 259 have not been met.
- 4. the procedure duplicates another provider's procedure.
- 5. the procedure is experimental, investigational, or part of a clinical trial.
- 6. the procedure is ordered by a judicial court for a recipient who is a ward of the county and is mentally incompetent.

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"Mentally incompetent individual" is defined in 42 CFR 441.251, revised October 1, 1999, as an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

7. the recipient is an institutionalized individual.

"Institutionalized individual" is defined in 42 CFR 441.251, revised October 1, 1999, as an individual who is either:

- i. involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or
- ii. confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

4.1.1 Essure System Contra-indications

The Essure System should not be used in any patient who:

- 1. is uncertain about her desire to end fertility;
- 2. can have only one micro-insert inserted (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus);
- 3. has previously undergone a tubal ligation; or
- 4. has any of the following conditions:
 - a. pregnancy or suspected pregnancy;
 - b. delivery or termination of a pregnancy less than six weeks before Essure micro-insert placement;
 - c. active or recent upper or lower pelvic infection;
 - d. known allergy to contrast media; or
 - e. known hypersensitivity to nickel, confirmed by skin test

4.2 Post-Procedure Hysterosalpingogram

Post-procedure HSG is not covered for any condition or diagnosis other than confirmation of occlusion of the fallopian tubes after the Essure sterilization procedure.

4.3 Sterilization Reversals

Medicaid does not cover reversal of sterilization. Examples of sterilization reversal procedures include reverse bilateral fallopian tube trans-section by means of bilateral salpingoplasty and reversal of a bilateral vasectomy by means of a bilateral vasovasostomy.

5.0 Requirements for and Limitations on Coverage

Important Note: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary to correct or ameliorate a defect, physical or mental

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illness, or a condition identified through a screening examination (**subject to prior approval requirements**, **if applicable**). For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy or visit the DMA Web sites specified below.

Basic Medicaid Billing Guide: http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT Provider Page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

5.1 Prior Approval

Prior approval is not required.

5.2 Federal Regulations

Federal regulations require the N.C. Medicaid program to obtain documentation prior to rendering a sterilization procedure indicating that the provider has complied with the requirements listed in 42 CFR 441.250 through 259. For sterilization procedures, this documentation must include a correctly completed consent form as explained in **Section 5.3**.

5.3 Sterilization Consent

The recipient must provide voluntary informed consent in accordance with Medicaid policy and the federal regulations listed in 42 CFR 441.257 and 258. The individual must be:

- 1. at least 21 years of age when s/he signs the consent form;
- 2. given the opportunity to ask, and receive answers to, questions concerning the procedure, and provided a copy of the consent form;
- 3. advised that the sterilization consent may be withdrawn at anytime before the sterilization procedure without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the recipient might otherwise be entitled;
- 4. counseled in alternative methods of family planning and birth control;
- 5. advised that the sterilization procedure is considered to be irreversible;
- 6. provided a thorough explanation of the specific sterilization procedure to be performed;
- 7. provided a thorough explanation of the possible discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;
- 8. provided a full description of the benefits or advantages that may be expected as a result of the sterilization;
- 9. provided suitable arrangements to ensure that information is effectively communicated if the recipient is blind, deaf, or otherwise handicapped;
- 10. provided an interpreter if the recipient does not understand the language used on the consent form or the language used by the person obtaining consent; and
- 11. permitted to have a witness of his or her choice present when the consent is obtained.

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5.3.1 Date of Consent

Consent must be obtained at least 30, but not more than 180, days prior to the date of the sterilization, except under the following circumstances.

- 1. Premature Delivery: Informed consent must have been given at least 30 days before the expected date of delivery, and at least 72 hours must have passed since the informed consent was given.
- 2. Emergency Abdominal Surgery: At least 72 hours must have passed since the informed consent was given.

5.3.2 Obtaining Consent

Informed consent for sterilization may not be obtained while the individual to be sterilized is:

- 1. in labor;
- 2. seeking to obtain or obtaining an abortion; or
- 3. under the influence of alcohol or other substances that affect the individual's state of awareness.

Any state or local requirements for obtaining consent, except those requiring spousal consent, must be followed.

5.3.3 Date of Confinement

The estimated date of confinement must be documented on the sterilization consent form in cases of premature delivery.

5.3.4 Consent Form

Providers must complete a valid sterilization consent form prior to rendering a sterilization procedure. The sterilization consent form is a federally mandated document and must be completed according to the instructions listed in **Attachment B,** Instructions for Completing the Consent Form.

Refer to **Attachment C** for a sample of the sterilization consent form.

A valid sterilization consent must be on file with DMA's fiscal agent before payment can be made for a sterilization procedure.

5.3.5 Signatures

Changed, altered, or traced-over signatures (either of the recipient or of the person obtaining consent) and/or dates are not acceptable on the consent form. The consent form must be voided and a new consent form must be initiated. A new consent form cannot be initiated after the sterilization.

The physician's signature must be dated on or after the date of service (procedure date). Handwritten signatures must be legible or the name must be printed below the written signature.

5.4 Interpreter Services

When telephone interpreter services are needed to complete the sterilization consent form for non-English-speaking Medicaid recipients, the interpreter's signature, date of the interpreter's service, and the language used must be documented on the sterilization

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consent form. In lieu of getting the interpreter's signature on the sterilization consent form at the time the service is provided, the interpreter who explains the procedure by telephone may fax or mail the attestation of interpreter services to the provider. Criteria for the faxed or mailed attestation are as follows:

- 1. The wording of the attestation should be taken directly from the sterilization consent form.
- 2. The interpreter must write his or her signature and the date the interpreter services were rendered on the attestation form.
- 3. The dates with the signatures of the recipient, interpreter, and person obtaining consent must all be the same.
- 4. The attestation form must include the recipient's name, as it appears on the Medicaid identification card, as well as the Medicaid identification number.
- 5. A copy of the attestation must be attached to the consent form when the provider submits the statement to Medicaid's fiscal agent.
- 6. The provider must maintain the original attestation document with the consent form in the patient's medical record.

5.5 Name Change Statement

A signed name change statement a must be provided to DMA's fiscal agent when the recipient name listed on the claim is different than the name on the sterilization consent form. The name change statement must verify that the names are for the same person. This statement should be written on the provider's office letterhead. (See **Attachment B**, Instructions for Completing the Consent Form.)

5.6 Limitations

Medicaid places reasonable unit limitations on procedures and services. When extenuating circumstances require a provider to exceed a unit limitation, the denied claim and medical records must be submitted as an adjustment for reconsideration. The following sterilization limitations apply:

- 1. Sterilization procedures are covered for an individual once in a lifetime unless documentation supports repeat due to failed procedure
- 2. Medicaid allows 100% reimbursement of the allowable on the fee schedule for a sterilization and vaginal delivery or sterilization and cesarean section when they are the only surgery procedures performed on the same date of service.
- 3. Dilation and curettage performed on same date of service as sterilization will be suspended for medical review. Medical records may be requested.

6.0 Providers Eligible to Bill for the Procedure

Providers who meet Medicaid's qualifications for participation and are currently enrolled with the N.C. Medicaid program to provide this procedure are eligible to bill for sterilization procedures when the service is within the scope of their practice.

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7.0 Additional Requirements

7.1 Claims Review

Manual review of sterilization claims is performed in accordance with CMS-approved guidelines to ensure that the procedure complies with federally mandated guidelines.

7.2 Claims Reimbursement

All provider types submitting claims for reimbursement, including any associated services following sterilization, will be denied or recouped if the sterilization consent form on file is invalid.

8.0 Policy Implementation and Revision Information

Original Effective Date: January 1, 1974

Revision Information:

Date	Section Revised	Change
	Sections 1.2, 4.1.1,	Coverage of the Essure System procedure and
	3.2, 4.2, and	the hysterosalpingogram procedure was added
	Attachment A	to the policy effective with date of
		implementation September 1, 2003.

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Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

1. CMS-1500 Claim Form

Physicians, Clinics, Health Departments, Planned Parenthood, and Nurse Practitioner providers enrolled in the N.C. Medicaid program bill services on the CMS-1500 claim form.

2. UB-92 Claim Form

Hospital providers bill services on the UB-92 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

The only diagnosis codes to be considered strictly for the purpose of elective sterilization are V25.2.

Note: All claims must be billed with ICD-9-CM diagnosis V25.2 as the primary or secondary diagnosis code on the claim.

C. Procedure Codes

Note: This list of codes may not be all-inclusive.

1. Physician Claims

Laparoscopic Procedures

58600	58605	58611	58615	58670	58671

Essure Procedure

58565

Note: For dates of services September 1, 2003 through March 31, 2004, the procedure is billed with CPT procedure code 58579; for dates of service April 1, 2004 through December 31, 2005, the procedure is billed with CPT procedure code S2255.

Hysterosalpingogram

58340

Note: CPT procedure code 58340 must be billed with procedure code 74740 **or** 76831.

Vasectomy Procedures

55250	55450

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2. Hospital Claims

63.70	63.71	63.72	63.73	66.21
66.22	66.29	66.31	66.32	66.39
87.82	87.83	68.19	RC278	

D. Modifiers

All providers, except ambulatory surgical centers, must append modifier FP to the procedure code when billing for sterilization procedures. Other modifiers must be used, as applicable.

E. Place of Service

Physicians' offices, ambulatory surgery centers, outpatient clinics, inpatient and outpatient hospitals.

F. Reimbursement Rate

Providers must bill their usual and customary charges.

G. Denied Claims

1. Additional Information Required

When a claim is denied with an EOB that indicates additional information is required (such as records to verify a procedure code or a date of service), the claim must be resubmitted with the requested documents and a copy of the valid consent form attached.

2. Undocumented Aliens

If an inpatient or outpatient hospital claims reimbursement for a sterilization procedure for an undocumented alien, the claim will be denied with a code indicating "recipient eligible for emergency services only." Providers must:

- a. resubmit the claim as an adjustment, placing non-emergent charges (such as sterilization) in the Non-Covered column, and
- b. note the change in the Remarks field.

Note: Failure to complete both the Non-Covered column and the Remarks field will result in denial.

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Attachment B: Instructions for Completing the Consent Form

A. Completing the Form

Following is the list of fields included in the federal consent form requirements for sterilization. All areas are required to be completed except area 9 (race) and areas 10, 11, and 12, if not applicable. Fields in bold print cannot be altered. This guide will assist in correct completion of consent forms and should help to decrease the number of denials related to errors in completing the form.

- 1. Person or facility that provided information concerning sterilization.
- 2. Type of sterilization procedure to be performed.
- 3. Recipient's date of birth (must be at least 21 years of age when the consent form is signed). Date of birth must match recipient files.
- 4. Name of recipient as it appears on the MID card.
- 5. The full name of the physician scheduled to do the surgery (abbreviations, initials, or "doctor on call" are unacceptable). May use "Physician on call for Any Provider OB/GYN clinic."
- 6. Type of sterilization procedure to be performed.
- 7. Recipient's signature (must be dated) cannot be altered, traced over, or corrected. Initials are not acceptable. Signature must be legible. If not, the recipient's name may be typed or printed under the signature.
- 8. Date the consent form was signed. The date of the recipient's signature must be at least 30 days and no more than 180 days prior to the date of the sterilization. The count begins the day following the recipient's signature date.
- 9. Race and ethnicity (not required).
- 10. Language in which the form was read to the recipient, if an interpreter was used.
- 11. Signature of the interpreter.
- 12. Signature date of the interpreter (same as # 8 and # 16).
- 13. Name of recipient.
- 14. Name of sterilization procedure.
- 15. Signature of person obtaining consent must be dated (see # 16) and legible. If not legible, the name must be typed or printed above or below the signature.
- 16. Date (this date must be the same as the recipient signature date). Note: the doctor can also be the person obtaining consent.
- 17. The full name and address of the facility, including street name and number, city, state, and zip code, where the consent was obtained and witnessed.
- 18. Name of recipient.
- 19. Actual date of sterilization. Date of surgery may be changed on consent form with submission of operative records verifying date of service.
- 20. Type of sterilization procedure performed.
- 21. The box is to be checked if the delivery was premature (write the recipient's expected delivery date in the space provided).

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- 22. The box is to be checked if emergency abdominal surgery was performed. Claim must be submitted with operative records.
- 23. Physician's signature must be legible or name must be printed below the signature. Signature cannot be initials.
- 24. Date must be on or after the date of service.

B. Abbreviations/Guide for Completion of Sterilization Consent Form

The following abbreviations are acceptable on the sterilization consent form as a description of the type of sterilization procedure:

BTF Bilateral tubal fulguration
BTS Bilateral tubal sterilization
BTC Bilateral tubal cauterization
BTL Bilateral tubal ligation
BPS Bilateral postpartum sterilization
PPBTL Postpartum bilateral tubal ligation

LTC Laparoscopic tubal cautery

Acceptable written wording:

Application of fallopian rings/laparoscopic

Elective cauterization of fallopian tubes

Hulka clip occlusion

Laparoscopic tubal ligation

Pomeroy

Modified Pomeroy

Parkland

Tubal banding

Tubal sterilization

Yeon rings

Essure system

Unacceptable wording (not specific to type of procedure):

Tubal occlusion
Tubal coagulation

C. Submitting Sterilization Consents Separately

When submitting sterilization consents separately from the claim, follow these instructions.

- 1. **Write the recipient's MID number** in the upper right corner of the consent form. Medicaid's fiscal agent must have the MID to enter the form into the system.
- 2. **Verify** that all the information on the form is correct.
- 3. Mail the consent to:

EDS

PO Box 300012

Raleigh NC 27622

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4. **Send only** sterilization consents submitted separately from the claim to PO Box 300012. Upon receipt, Medicaid's fiscal agent will review the consent to ensure adherence to federally mandated guidelines.

5. File claims electronically, or mail paper claims submitted without a consent to:

(Physicians) (Hospitals) EDS EDS

PO Box 30968 PO Box 300010 Raleigh NC 27622 Raleigh NC 27622

D. Name Change Policy for Surgical Procedures

If the recipient name on the claim and the name on the sterilization form are different, a signed name change statement verifying that they are the same person must be included (refer to example below).

E. Name Change Statement (Example)

Dr. Any Provider 101 Any Hwy Any City NC 22222

Medicaid ID Number: 8888888T

To Whom It May Concern:

Jane Recipient has changed her name to Jane Doe.

Dr. Any Provider (Signature of representative at provider's office is required)

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Attachment C: The Consent Form

Copies of the form may be obtained from the Medicaid fiscal agent.

CONSE	NT FORM MID #
	WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY
CONSENT TO STERILIZATION	STATEMENT OF PERSON OBTAINING CONSENT
I have asked for and received information about sterilization from (1) (dector or othic) (dector or othic)	Before (13) signed the
the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.	operation (14) the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it. I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that
I UNDERSTAND THAT THE STERILIZATION MUST BE CON- SIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN. OR FATHER CHILDREN.	sterilization is different because it is permanent. I informed the inclividual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds. To the best of my knowledge and belief the individual to be sterilized is at least 21-years old and appears mentally competent.
I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.	sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.
I understand that I will be sterilized by an operation known as a	(15)
associated with the operation have been explained to me. All my questions have been answered to my satisfaction.	Signature of person obtaining consent (1.7) Facility
I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterifized will not result in the withholding of any benefits or medical services provided by federally funded program. I am at least 21 years of age and was born on (3)	PHYSICIAN'S STATEMENT Shortly before 1 performed a sterilization operation upon
I, (4) Menth Day Year I, hereby consent	(18) on (19) Name of implication to be serviced (19 cont [†] d) explained to him/her the nature of the operation
of my own free will to be sterilized by (5) (decay) by a method called (6) My consent expires 180 days from the date of my signature below. I also consent to the release of this form and other medical records about the operation to: Representatives of the Department of Health, Education, and Welfare or Employees of programs or projects funded by that Department but only for determining if Federal laws were observed. I have received a copy of this form. (7) Signature You are requested to supply the following information, but it is not required: (9) Race and sthrictly designation (piesse check) Alercican Indian or Elack (not of Hispanic origin)	sterilization operation it is intended to be a final and irreversible procedure and he discomforts, risks and benefits associated with it. I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent. I informed the individual to be sterilized that his/her consent can be withdrawn at an any time and that he/she will not lose any health services or benefits provided by Federal funds. To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure. (Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be
Alaska Native	used. Cross out the paragraph which is not used.) (1) At least thirty days have passed between the date of the in- dividual's signature on this consent form and the date the steriliza- tion was performed. (2) This sterilization was performed less than 30 days but more
(if an interpreter-is provided to assist the individual to be starilized) I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent, I have also read him/her the consent form in (10) language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.	than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested): (21) Premature delivery (22) Individual's expected date of delivery: (describe circumstances):
(11) (12)	(23) (24)
372-116 Interpreter Option Continue Con	Physician Date